REMARKS

I. Petition for Extension of Time

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office Action mailed December 1, 2006 for two (2) months from March 1, 2007 to May 1, 2007. Authorization is given to charge the extension of time fee of $450.00 (37 C.F.R. §1.136 and §1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

II. Claim Amendments

Claim 1 has been amended to clarify that the semipermeable membrane of the claimed dosage form is comprised of a single polymer composition. According to amended claim 1, the polymer composition contains a water insoluble polymer capable of forming a semipermeable membrane and a modifying agent.

Support for the claim amendment is provided by the specification at page 8, lines 6-7, which provides that the membrane comprises a water insoluble polymer and a modifying additive. This is consistent with Example 3 which shows a pharmaceutical core that is coated with a semipermeable membrane composition prepared from ethyl cellulose (a water-insoluble polymer capable of forming a semipermeable membrane), ethanol and talc (modifying agent). In that example, ethyl cellulose is the single polymeric component of the semipermeable membrane composition. As such, the claim amendment does not introduce new matter.

Furthermore, Applicants respectfully submit that the claim amendment satisfies the written description requirement as set forth in 35 U.S.C. §112, first paragraph. Possession of the claimed invention as defined by amended claim 1 is shown by Example 3 which illustrates an actual reduction to practice and by original claim 16 which defines a semipermeable membrane comprised of a water insoluble polymer and a modifying agent. .

New claims 30 and 31 correspond to original claims 11 and 19, respectively, which had previously been canceled.

III. Claim Rejections – 35 U.S.C. §103(a)

A. US 6,245,351 to Nara et al. ("Nara") in view of US 5,225,202 to Hodges et al. ("Hodges")

Claims 1, 3, 6-8, 12-18, 20 and 25-29 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Hodges.

The claimed invention is characterized by a semipermeable membrane comprising a single polymer composition containing a water-insoluble polymer capable of forming a semipermeable membrane. Nara neither discloses nor suggests this feature of the claimed invention.

Nara's coating composition is comprised of a water-insoluble substance, a swellable polymer and an optional hydrophilic substance (See claims 1 and 9). Examples of the water-insoluble substance are disclosed at column 4, lines 5-25, e.g., a cellulose ether, an acrylic polymer, a hydrogenated oil, a wax, etc. Examples of the swellable polymer are disclosed at column 4, lines 32-59, e.g., hydroxypropyl cellulose ("HPC"), crosslinked acrylic polymers, etc. Examples of the hydrophilic substance are disclosed at column 4, line 64 to column 5, line 8, e.g., hydroxypropylmethyl cellulose ("HPMC").

When the water-insoluble substance of Nara is a polymer, e.g., a cellulose ether, an acrylic polymer, etc., Nara's coating composition contains at least two polymers: the water-insoluble polymer and the swellable polymer. Such a two-polymer system does not suggest the single polymer coating composition of the claimed invention.

When the water-insoluble substance of Nara is not a polymer, e.g., a hydrogenated oil, wax, etc., Nara does not disclose or suggest that the swellable polymer must be both water-insoluble ***and*** capable of forming a semipermeable membrane. In this regard, the Examiner's attention is directed to Nara's disclosure at column 4, lines 32-59, of the following two broad categories of swellable polymers:

> The swellable polymer for the present invention, which has no basic groups, is exemplified by polymers showing little pH dependency in swelling and polymers having an acidic dissociating group and showing pH-dependent swelling.
>
> Of these swellable polymers, those having an acidic dissociating group such that little swelling occurs at acidic pH levels as in the stomach and increased swelling occurs at neutral pH levels as in the small and large intestines is preferably used.

> Examples of the polymers shows little pH dependency in swelling include hydroxypropyl celluloses, such as high-viscosity hydroxypropyl cellulose (viscosity about 1,000 to about 4,000 cp in 2% aqueous solution at 200° C.) and low-substitutional hydroxypropyl cellulose; etc.
>
> Examples of the polymers having an acidic dissociating group, and showing pH-dependent swelling include crosslinked acrylic polymers, such as Carbomer™ 934P, 940, 941, 974P, 980 and 1342, polycarbophil, calcium polycarbophil (all produced by BF Goodrich Company), and HIVISWAKO™ 103, 104, 105 and 304 (all produced by Wako Pure Chemical). The viscosity of such pH-dependent swelling polymer is about 1,500 to about 60,000 cp in 0.2% neutral solution, preferably about 3,000 to about 50,000 cp. Molecular weight is about 1,000,000 to about 10,000,000, preferably about about 1,000,000 to about 5,000,000, and more preferably about 1,000,000 to about 3,500,000.

The first category, i.e., swellable polymers which do not have any basic groups, is illustrated by HPC, a known film forming agent. However, HPC is water soluble. Therefore, when Nara's water-insoluble substance is not a polymer, this first category of swellable polymers as illustrated by HPC does not meet the claim requirement that the single polymer coating composition is water-insoluble and capable of forming a semipermeable membrane.

The second category, i.e., swellable polymers having an acidic dissociating group, is illustrated by the following cross-linked acrylic polymers: Carbomer (water soluble); polycarbophil and calcium polycarbophil (incapable of forming a semipermeable membrane); and HIVISWAK carboxyvinyl polymers (hydrophilic/water soluble). Therefore, when Nara's water-insoluble substance is not a polymer, this second category of swellable polymers as illustrated by Carbomer, polycarbophil, calcium polycarbophil and HIVISWAK, does not meet the claim requirement that the single polymeric component of the single polymer coating composition is water-insoluble and capable of forming a semipermeable membrane.

Furthermore, all of the working Examples 1-11 are directed to a coating composition containing 2-3 polymers:

(1) ethyl cellulose as the water-insoluble polymeric component;

(2) Carbomer/HIVISWAK as the water soluble, swellable polymer; and

(3) optionally hydroxypropylmethyl cellulose as the hydrophilic polymer.

In summary, Nara discloses a coating composition comprising at least two polymers: a water-insoluble polymer and a swellable polymer. When the water-insoluble substance is not a polymer, e.g., a wax or oil, Nara discloses a swellable polymer that is either water soluble or water-insolublc but not capable of forming a semipermeable membrane. Thus, it can be said that Nara teaches away from the claimed invention which is characterized by a semipermeable membrane comprising a single polymer composition containing a water-insoluble polymer capable of forming a semipermeable membrane.

The Examiner relies on the disclosure by Hodges of an enteric-coated tablet core containing the active and a buffering agent within the range of from about 1 to about 20% by weight (col. 3, lines 20-26). As such, Hodges fails to overcome the failure of Nara to suggest the claimed invention.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established. Accordingly, withdrawal of the §103 rejection of claims 1, 3, 6-8, 12-18, 20 and 25-29 based on the combination of Nara and Hodges is requested.

B. Nara, Hodges and US 4,795,644 to Zentner ("Zentner") or US 6,013,281 to Lundberg et al. ("Lundberg")

Claims 9 and 10 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Hodges and Zentner or Lundberg.

Zentner is cited by the Examiner for the alleged disclosure of sodium mono- or di-phosphate as a pH modifying agent. Lundberg is cited for the disclosure of arginine as an alkaline reacting compound.

Claims 9 and 10 are directly or indirectly dependent on claim 1. For all of the reasons given in Section II(A), above, there would have been no motivation at the time the claimed invention was made to combine Nara and Hodges to arrive at the claimed invention, for example as defined by claim 1. Neither Zentner nor Lundberg overcomes the failure of the combination of Nara and Hodges to establish a *prima facie* case of obviousness. Accordingly, withdrawal of the §103 rejection of claims 9 and 10 is requested.

C. Nara, Hodges and WO 98/54171 ("Cotton")

Claims 4, 5 and 23-26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Hodges and Cotton.

As stated by the Examiner on page 5 of the Office Action, Cotton is cited for the disclosure of the magnesium salt of S-omeprazole as an active ingredient. Applicants submit that Cotton does not over come the deficiencies of Nara and Hodges to establish a *prima facie* case of obviousness for the reasons given in Section II(A). Withdrawal of the §103 rejection of claims 4, 5 and 23-26 is requested.

CONCLUSION

Applicants have made a good faith attempt to respond to the Office Action. It is respectfully submitted that claims 1, 3-10, 12-18, 20 and 23-31 are in condition for allowance, which action is earnestly solicited.

Any fees due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: April 11, 2007

Respectfully submitted,

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